Clinical Effects of Spinal Heat Massage Device Incorporating Spinal Twisting Massage Technique on Chronic Mechanical Pain and Functional (or Disability) Improvement

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Clinical Effects of Spinal Heat Massage Device Incorporating Spinal Twisting Massage Technique on Chronic Mechanical Pain and Functional (or Disability) Improvement

Directed by Professor Sung Hoon Kim

A Dissertation Submitted
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and the Graduate School of Yonsei University
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July 2024

This certifies that the Dissertation
of Syung Hyun Cho is approved.

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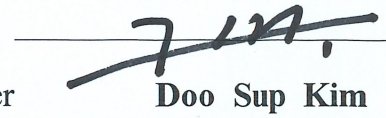

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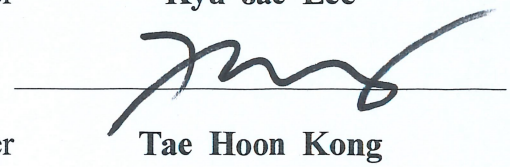

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The Graduate School
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July 2024

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July, 2024

Syung Hyun Cho

TABLE OF CONTENTS

LIST OF FIGURES ····· ii

LIST OF TABLES ····· iii

ABSTRACT IN ENGLISH ····· v

1. Introduction ····· 1

2. Materials and Methods ····· 5

2.1. Research subjects ····· 6

2.2. Treatment Devices ····· 10

2.3. Clinacal Trial Protocol Design ····· 12

2.3.1. Visual Analog Scale (VAS) ····· 15

2.3.2. the Korean Western Ontario and McMaster Univerisy index (K-WOMAC index) ····· 16

2.3.3. Pressure Pain Threshold (PPT) ····· 19

2.3.4. Measurement of Anatomical Functional Changes through General Radiography ····· 20

2.4. Statistics ····· 21

3. Results ····· 22

3.1. Analysis results at each time points for evaluation variables ····· 22

3.2. The results of temporal changes for evaluation variables ····· 24

3.3. The results of temporal changes for each variables ····· 25

3.3.1. The results of VAS Analysis Using the LMM Model ····· 25

3.3.2. The results of K-WOMAC Analysis Using the LMM Model ····· 27

3.3.3. The results of PPT Analysis Using the LMM Model 29
3.3.4. Analysis Results of Anatomical Changes via Standard radiographic 31
3.3.5. Analysis of Safety Evaluation 32
4. Discussion and Conclusion 33
REFERENCES 37
ABSTRACT IN KOREAN 43

LIST OF FIGURES

<Fig 1> Clinical Trial Design ····· 6
<Fig 2> Device used in the clinical trial ····· 10
<Fig 3> Treatement devices and how to use it ····· 11
<Fig 4> Test and Treatment Protocol ····· 14
<Fig 5> Visual Analog Scale (100mm) ····· 15
<Fig 6> K-WOMAC Scores ····· 17
<Fig 7> WOMAC and K-WOMAC questionare ····· 18
<Fig 8> Example of PPT (Pressure Pain Threshold) Measurement ····· 19
<Fig 9> Anatomical analysis ····· 20
<Fig 10> VAS changes according to time (week) ····· 26
<Fig 11> K-WOMAC changes according to time (week) ····· 28
<Fig 12> PPT changes according to time (week) ····· 30
<Fig 13> Anatomical analysis result using x-ray imaging ····· 31

LIST OF TABLES

<Table 1> include and Exclude criteria ····· 8

<Table 2> Characteristics of subjects ····· 8

<Table 3> Characteristics of cont. group vs. exp. group. ····· 13

<Table 4> characteristics of overall variables ····· 23

<Table 5> the mean value changes from the baseline to 4 and 6 week ····· 24

<Table 6> Results of VAS Change Analysis ····· 25

<Table 7> Results of K-WOMAC Change Analysis ····· 27

<Table 8> Results of PPT Change Analysis ····· 29

ABSTRACT

Clinical Effects of Spinal Heat Massage Device Incorporating Spinal Twisting Massage Technique on Chronic Mechanical Pain and Functional (or Disability) Improvement

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(Directed by Professor Sung Hoon Kim)

Background and Objective

The prevalence of chronic nonspecific low back pain is increasing, leading to a rapid rise in the use of therapeutic interventions involving various massage devices. Nevertheless, there is limited research on the mechanisms, especially those involving spinal twisting. This study sought to assess the effect of heat and spinal twisting massage method on people with chronic nonspecific low back pain.

Methods

A total of 36 participants were allocated into two groups: an experimental (n=18) and a control group (n=18). The experimental group underwent heat therapy and spinal twisting

massages twice weekly for 4 weeks, while the control group received heat therapy combined with traditional vibration massage techniques. Outcomes were evaluated using the Visual Analog Scale (VAS), Pressure Pain Threshold (PPT), The Korean version of Western Ontario and McMaster Universities Osteoarthritis Index (K-WOMAC), spinal inclination, and Cobb's angle.

Results

Significant improvements in VAS, K-WOMAC, and PPT scores were observed at three different time points in both groups. Notably, the experimental group exhibited a significantly greater reduction in VAS scores in comparison with the control group (p-value: 0.0369), indicating superior pain relief in the experimental group. Although improvements in K-WOMAC and PPT scores were noted within the experimental group, these did not reach statistical significance. Furthermore, there were no significant changes in spinal inclination and Cobb's angle from baseline to week 6.

Conclusion

The study confirmed that combining heat therapy with spinal twisting massage effectively alleviates pain and enhances daily functional abilities in patients with chronic nonspecific low back pain. This combined treatment was found to be more effective than traditional heat therapy and vibration massage, suggesting its potential as a novel treatment option over existing conservative therapies. The findings indicate that heat and spinal twisting massage may boost autonomic nervous system activity, thereby aiding in pain relief and improved physical activity.

Limitations

This study has several limitations. It did not explore long-term outcomes or possible variations in treatment responses among different patient subgroups. Additionally, the

effects of other conservative therapies or interventions were not compared to spinal twisting massage and heat therapy. Future studies should involve long-term clinical trials with varied participant age groups, larger sample sizes, and different treatment frequencies, as well as investigate the physiological and biochemical mechanisms to further enhance treatment efficacy.

Keywords: spinal twist massage, heat therapy, chronic non-specific spinal pain, Visual Analog Scale, Korean Western Ontario and McMasters Universities

1. Introduction

In modern society, the majority of individuals experience prolonged periods of sitting and decreased physical activity. The prevalent use of smart devices has exacerbated issues related to poor posture and elevated stress levels, contributing to an increase in spinal pain and discomfort. This trend is reflected in the growing number of patients seeking medical services, indicating a sustained rise in the demand for healthcare.[1,2] Decreased physical activity, along with spinal pain and issues, significantly affects individuals' daily lives. Furthermore, these conditions contribute to reduced productivity, increased sick leave, and rising healthcare costs, thereby imposing substantial economic burdens on both societal and economic levels.[4,5]

In a 2019 analysis by Cieza and team on the global impact of risk factors, injuries about chronic spinal pain, such as lower back pain, was found to be the most widespread health issue, greatly contributing to global disability.[3]

Spinal disorders include clearly defined conditions such as muscle sprain, herniated discs, facet joint syndrome, and spinal stenosis. Among these, muscle sprain is the most common cause of pain.[6] However, a significant number of patients reporting spinal pain present with multifactorial etiologies, making diagnosis challenging. These patients suffer from non-specific spinal disorders where the exact cause of pain is unclear. Non-specific spinal disorders are more prevalent in women than in men, although the reasons for this remain unidentified. Consequently, treatment for patients who have non-specific spinal disorders primarily focuses on symptom reduction, employing a diverse array of

treatment methods.[7]

Conservative treatment methods are generally used to relieve spinal pain, which can be categorized into physical and non-physical methods. Physical therapy methods include direct stimulation techniques such as heat, massage, TENS, ultrasound, low level laser, and traction therapy. Non-physical therapy methods encompass cognitive behavioral therapy and pharmacological treatments. Additionally, commonly used pathological treatment modalities in clinical practice include injection therapy and electrical therapy.[8,9]

One of the prominent pain management therapies, heat therapy, works by dilating blood vessels, thereby increasing blood flow and promoting circulation. This enhanced circulation boosts catabolism, removes uric acid and acidic waste products from muscle cells, and helps eliminate lactic acid, free fatty acids, and subcutaneous fat. Heat therapy is thought to alleviate symptoms of aging and tiredness through these mechanisms, leading to pain-relieving effects. Clinically, heat-therapy has been demonstrated to be beneficial in alleviating pain and addressing injuries in various muscles and skeletal structures including lower back, spine, and shoulders. It has proven efficacy in varisous therapeutic programs utilizing heat therapy for pain relief.[10]

Another prominent treatment modality for addressing various musculoskeletal discomforts, encompassing non-specific spinal pain, is massage therapy.[11] Massage therapy has been extensively developed and utilized across different civilizations in Asia, including China and India, and its historical use can also be traced back to ancient Egyptian civilization.[12] In 2015, Furlan and colleagues conducted a comprehensive review of existing research databases, confirming that massage therapy provides significant short-term improvements in function and pain relief

for individuals experiencing acute and chronic spinal pain, especially when compared to inactive control treatments.[13]

Since the late 1990s, Spinal Thermal Massage Devices (STMDs), engineered to simultaneously deliver heat and massage effect to the spine, have been introduced to the market. These devices have evolved in various forms and continue to be developed and released. STMDs combine heat therapy with precise mechanical massage therapy to relieve muscle tension and improve blood circulation, thereby enhancing spinal health. By providing potential relief effects, STMDs have become a significant non-invasive treatment option for spinal pain syndromes, which affect millions of people worldwide.[14,15,16] As STMDs have become widely used, research has been conducted to clinically validate their effectiveness. Lee and colleagues found that the use of STMDs has a positive impact on reducing depression and stress.[18] As STMDs have become widely used, research has been conducted to clinically validate their effectiveness. Lee and colleagues found that the use of STMDs has a positive impact on reducing depression and stress. Additionally, previous studies have shown that the use of these devices alleviates pain in areas such as the neck, shoulders, and pelvis. Such research efforts are ongoing to confirm the efficacy of STMDs in pain relief and spinal health across various populations.[17]

Recently, a new form of equipment has been introduced that applies spinal twisting massage techniques to the existing STMD technology. However, clinical studies on the efficacy of STMDs incorporating massage that involves twisting the spine are yet to be conducted.

Therefore, this study intends to evaluate the clinical effectiveness of using STMDs that combine heat and spinal twisting massage in patients who have

chronic non-specific spinal pain. The main goal of this research is to verify the pain relief characteristics of STMDs with spinal twisting massage in patients who have chronic non-specific spinal pain. Additionally, the study compares the therapeutic efficacy of this new device with that of traditional STMDs that combine heat and simple vibration massage. Through this research, we seek to bridge the divide between cutting-edge technology and easily obtainable healthcare methods, ensuring more effective and safe management of spinal pain.

2. Materials and Methods

The clinical trial was designed to evaluate the effectiveness and superiority of spinal twisting massage techniques in patients with chronic non-specific spinal pain, focusing on pain relief, improvement in daily functional activities, and anatomical improvement as observed in general radiographic imaging. The study was structured as an active control, randomized, single-blind trial. Prior to commencement, the trial was authorized by the Institutional Review Board (IRB) of Yonsei University Wonju Christian Hospital (IRB approval number CR223008) and was carried out in compliance with the Declaration of Helsinki.

The trial included both experimental and control groups, with each group undergoing clinical treatment for a total of six weeks. The entire process, from participant recruitment to statistical analysis and data compilation, spanned approximately three months, from June 21, 2023, to September 23, 2023.

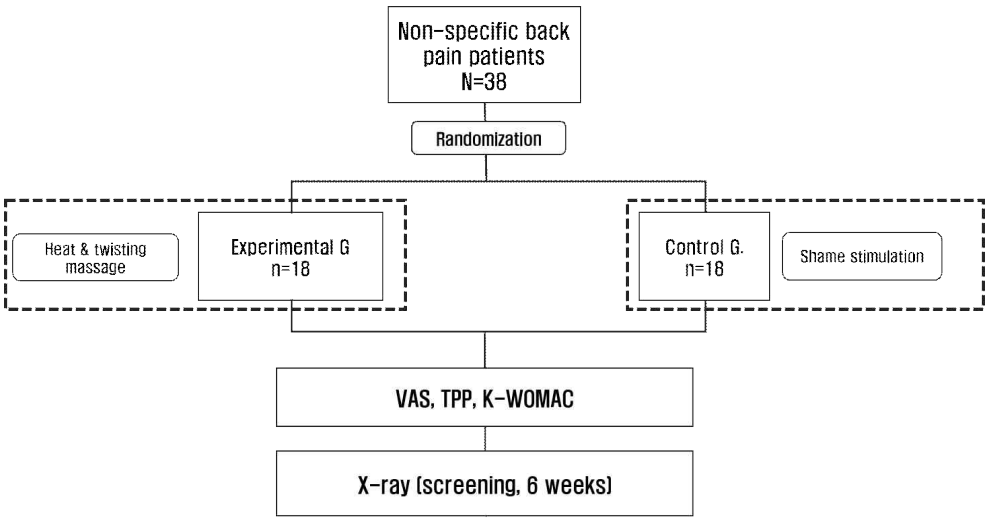


Figure 1. Clinical Trial Design

2.1. Research subjects

Participants for the clinical trial aimed at verifying the clinical efficacy of the STMD with spinal twisting massage were recruited from patients receiving clinical treatment for chronic non-specific spinal pain. Eligible participants had a Korean Western Ontario and McMaster Universities Osteoarthritis Index (K-WOMAC) score of 30 or higher, and an overall pain score of no less than 40 mm on the Visual Analog Scale (VAS). The selection criteria are detailed in Table 1.

Participants were excluded if they had undergone spinal surgery or procedures within the last three months, or if they had conditions that could potentially influence the treatment outcomes, as specified in the exclusion criteria in Table X. Prior to selection, participants were given a comprehensive explanation of the

study's purpose and methods. They voluntarily signed an informed consent form to participate in the study.

The study was conducted with two groups: the experimental group received spinal torsion massage STMD (st-STMD) while the control group received simple vibration massage STMD (v-STMD). The statistically appropriate sample size for evaluating clinical efficacy was assessed to be 16 participants in total, based on prior calculations[23]. Taking into account a dropout rate of 10%, the final sample size was calculated to be 18 participants per group. Therefore, a total of 36 subjects (mean age 64.97 ± 8.7 years, minimum age 40 years, maximum age 78 years) participated in this clinical study. The characteristics of the participants are shown in Table 2.

Table 1. Inclusion and Exclusion criteria

Inclusion Criteria	Exclusion Criteria
✓ Participants identified as having chronic non-specific spinal pain.	✓ Underwent spinal procedures or surgery in the last 3 months.
✓ Age between 20 and 80 years.	✓ Persistent inflammatory conditions, including ankylosing spondylitis.
✓ A Visual Analog Scale (VAS) score of 40 mm or higher (out of a maximum of 100 mm).	✓ The presence of other diseases that could potentially interfere with treatment efficacy.
✓ A K-WOMAC score of 30 or above.	✓ Patients who have taken immunosuppressants such as Cyclosporine A or Azathioprine within 6 weeks prior to screening.
✓ Participants with spinal pain persisting for more than 6 months.	✓ Individuals with psychological or mental disorders that could affect participation in the clinical trial.
✓ Participants with limb asymmetry were included from this research.	

Table 2. Characteristics of subjects

Classification		Total
Age	Mean (SD)	64.97 (8.7)
	Min / Max	40 / 78
Gender	Male (%)	7 (19.44)
	Female (%)	29 (80.56)

All subjects were restricted and prohibited from using corticosteroids, whether oral or non-oral, NSAIDs (non-steroidal anti-inflammatory drugs), concurrent surgeries, medications, other physical therapies, or medical devices that could imfact the clinical trial outcomes during the study period. If subjects experienced intolerable pain throughout the clinical trial period, rescue medication was permitted. Rescue medication was allowed every 6 hours, and participants were instructed not to exceed four tablets within 24 hours, as exceeding the maximum daily dose of 2600 mg of acetaminophen could cause liver damage. Medication records were monitored.

Given the potential influence and bias of acetaminophen on the efficacy evaluation, a washout period of five times, the minimum biological half-life (1-4 hours) was established, resulting in a 24-hour washout period (half-life 4 hours×6). Participants were instructed not to take rescue medication within 48 hours prior to efficacy assessment visits 2, 3, and 4. Additionally, participants were required to self-assess utilizing the VAS prior to taking rescue medication and documenting it in their diaries.

2.2. Treatment Devices

To evaluate the effects of thermal and spinal torsion massage, the automatic STMD N7 (model name: N motion pro, NUGA BEST Co., South Korea) was used as the treatment equipment. The control group utilized equipment with the same appearance, but without the rotational massage function, providing only simple vibration massage and thermal effects through horizontal/vertical movements using the automatic STMD equipment. The STMD N7 is a medical device certified by the Korean Ministry of Food and Drug Safety, ensuring a high level of safety reliability for the clinical trial participants.

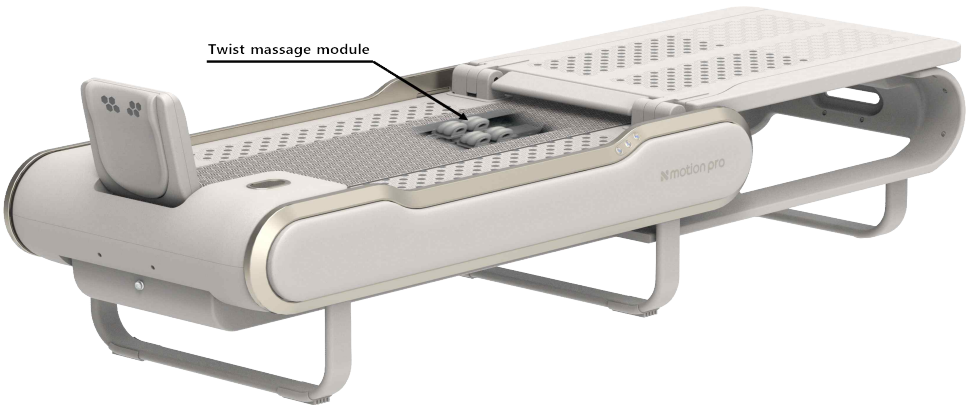


Figure 2. Device used in the clinical trial

In the spinal torsion massage protocol, the movement of the roller simulates the effect of pressing and twisting the spinal joints with two fingers, combined with the traction effect from the roller's vertical movement, providing rotational motion benefits to the spinal joints. The maximum height difference due to the roller's vertical movement is 45mm, and the additional rotational pressure from the roller's zigzag rotational movement is provided by a height difference of approximately 12mm. To eliminate any operational errors, all equipment was operated by designated researchers. Both the experimental and control group equipment operated automatically for approximately 30 minutes after initiation, providing participants with thermal and massage therapy. The actual usage of the equipment by the participants can be observed in Figure 3.

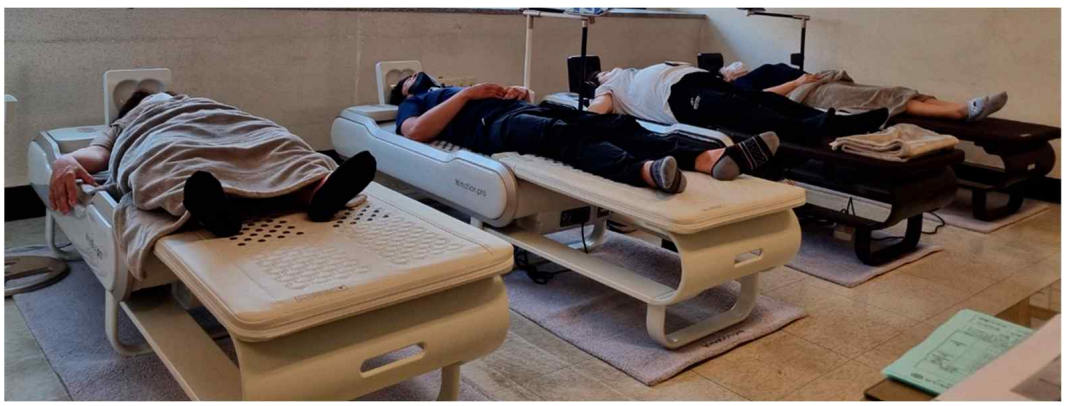


Figure 3. Treatement devices and how to use it

2.3. Clinical Trial Protocol Design

The researchers participating in the clinical trial were divided into unblinded personnel tasked with random participant assignment and implementation, and blinded evaluators responsible for assessing the clinical trial outcomes. Participants were selected from patients who wished to participate in the clinical trial and met all the inclusion and exclusion criteria previously outlined. The 36 selected participants provided informed consent during the initial visit and were randomly assigned a randomization number according to the order of registration, ensuring equal distribution into the experimental or control group. The randomization numbers of the assigned participants were managed by an unblinded researcher until participant registration was completed. All participants were blinded to their group allocation and the massage method used, with no related information disclosed to them. Additionally, participant diaries were distributed to evaluate the intake of rescue medication for those experiencing severe pain.

Participants were randomly allocated to either the experimental group or the control group, with each group receiving a different type of STMD treatment. The experimental group received st-STMD, which included torsion massage, whereas the control group received v-STMD, which provided simple vibration massage. The design of the study, including the number of participants, duration, and measurement factors, was based on a thorough review of relevant results from previously conducted studies and an analysis of their relation to this research to ensure a solid foundation for the study's execution.[19,21-26]

The mean ages of the experimental group and control groups were 64.22 ±

9.67 years and 65.72 ± 7.82 years, respectively. In the experimental group, 83.33% (15 participants) were female, and in the control group, 77.78% (14 participants) were female. There were no statistically significant differences between the two groups.

Table 3. Characteristics of control vs. experimental group.

Classification		Total	Control	Experimental	*p*-value
Age	Mean (SD)	64.97 (8.7)	65.72 (7.82)	64.22 (9.67)	0.6221
	Min / Max	40 / 78	45 / 78	40 / 78	
	Median (IQR)	67 (9)	67 (8)	67.5 (9)	
Gender	Male (%)	7 (19.44)	4 (22.22)	3 (16.67)	0.6737
	Female (%)	29 (80.56)	14 (77.78)	15 (83.33)	

Participants received STMD treatment twice a week for 30 minutes per session over a period of 4 weeks, in accordance with the study protocol. Safety and efficacy of the treatment were evaluated at the initial application, after 4 weeks, and after 6 weeks of treatment. To eliminate bias and errors in data analysis, all participant data were collected and evaluated at the end of the 6-week visit.

For the clinical efficacy evaluation of this study, the following measurement variables were used: the Visual Analog Scale (VAS) for pain, Pressure Pain Threshold (PPT) for tenderness, and the K-WOMAC score for assessing daily living functions. Additionally, standard radiographic imaging was performed during the first visit (week 0) and the last visit (week 6) to conduct secondary evaluations of spinal structural changes.

Figure 4. Test and Treatment Protocol

2.3.1. Visual Analog Scale (VAS)

Participants were asked to self-assess their spinal pain levels using a 100mm Visual Analog Scale (VAS) at three time points: before the STMD treatment, at the 4-week mark after the initial treatment, and at the final visit (6 weeks). The VAS is a tool for evaluating the subjective intensity of pain experienced by the patient, where 0 indicates no pain and 100 represents the worst pain imaginable. To minimize factors that might influence participants' perception of pain, all participants were allowed to rest and relax for 10 minutes before indicating their pain level on the scale.[27]

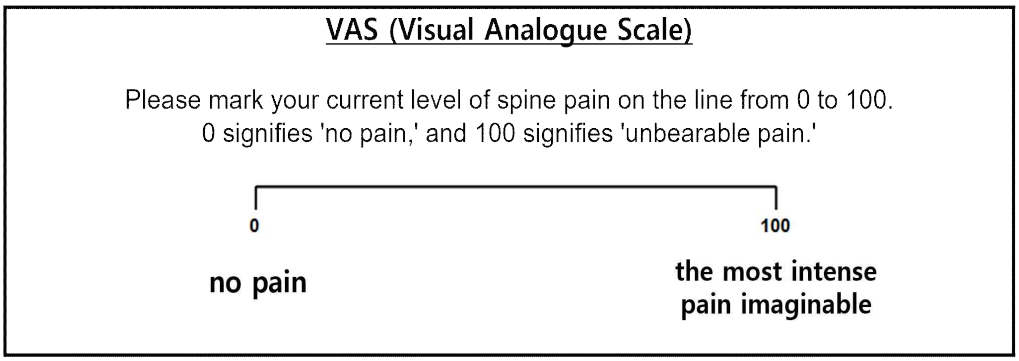


Figure 5. Visual Analog Scale (100mm)

2.3.2. the Korean Western Ontario and McMaster Univerisy index (K-WOMAC index)

The WOMAC (Western Ontario and McMaster Universities Arthritis Index) is a disease-specific tool used for the clinical assessment of health status changes related to pain. It is capable of measuring the clinical outcomes of treatment in patients experiencing spinal pain. By asking questions pertaining to spinal issues, it allows for a detailed and integrated evaluation of pain severity and the extent of functional limitations due to disability. Therefore, it is known as a specialized index for assessing improvements in pain and function related to spinal conditions .[34]

The Korean version of the WOMAC (K-WOMAC) Osteoarthritis Index, first translated and validated by Bae and his colleagues, is a questionnaire tool used for assessing pain-related conditions and is the most widely used instrument for evaluating functional status in clinical settings.[35] The K-WOMAC Index is extensively utilized owing to its strong validity and sensitivity to changes, and it is noted for its high reliability.

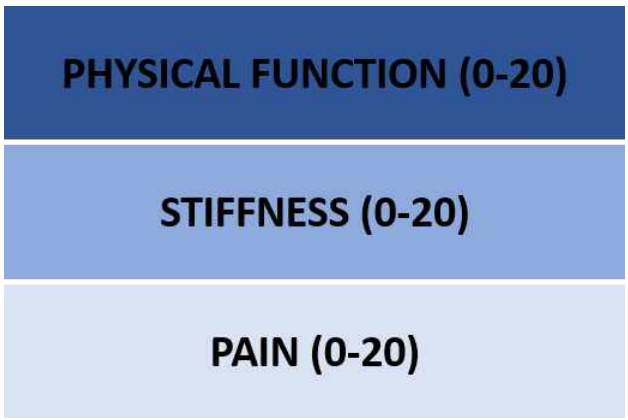


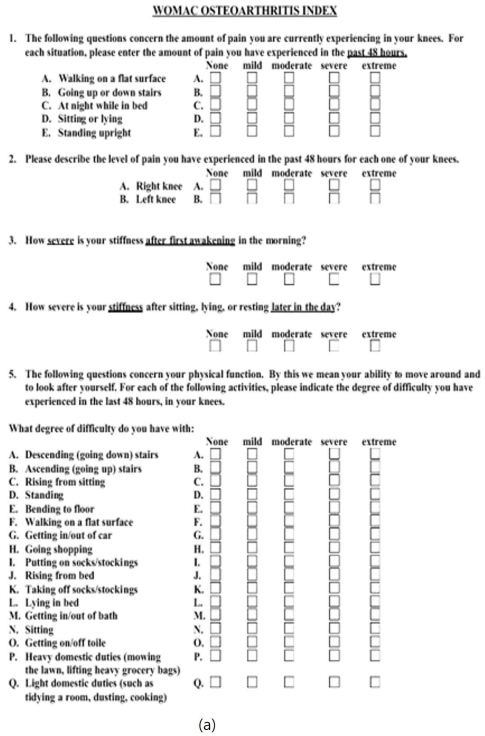
Figure 6. K-WOMAC Scores

The K-WOMAC assessment consists comprising questions related to functional limitations associated with pain and is comprised of 24 items divided into three subscales. These include 5 items on pain, and 17 items on physical capabilities, 2 items on stiffness, allowing for a comprehensive evaluation of overall knee pain and functional disability.

In this research, the K-WOMAC was employed to measure variations in pain, physical function, and stiffness indices at 4 weeks and 6 weeks, relative to the baseline (0 weeks). The measurement items include 5 pain-related activities, 2 stiffness items, and 17 physical activities, with higher scores indicating worsening symptoms and increased activity limitations.

Participants completed the questionnaire themselves, assessing their condition over the past 48 hours. Each item was scored using a 5-point Likert scale (0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe). The participants recorded their scores on the questionnaire, with the pain subscale consisting of 5 items (ranging from 0 to 20 points), the stiffness subscale consisting of 2 items

(ranging from 0 to 8 points), and the physical function subscale consisting of 17 items (ranging from 0 to 68 points). The total K-WOMAC score, representing the sum of these three subscales, ranged from 0 (no symptoms) to 96 (most severe symptoms), with each item equally weighted.



WOMAC OSTEOARTHRITIS INDEX

1. The following questions concern the amount of pain you are currently experiencing in your knees. For each situation, please enter the amount of pain you have experienced in the past 48 hours.

		None	mild	moderate	severe	extreme
A. Walking on a flat surface	A.	☐	☐	☐	☐	☐
B. Going up or down stairs	B.	☐	☐	☐	☐	☐
C. At night while in bed	C.	☐	☐	☐	☐	☐
D. Sitting or lying	D.	☐	☐	☐	☐	☐
E. Standing upright	E.	☐	☐	☐	☐	☐

2. Please describe the level of pain you have experienced in the past 48 hours for each one of your knees.

		None	mild	moderate	severe	extreme
A. Right knee	A.	☐	☐	☐	☐	☐
B. Left knee	B.	☐	☐	☐	☐	☐

3. How severe is your stiffness after first awakening in the morning?

None	mild	moderate	severe	extreme
☐	☐	☐	☐	☐

4. How severe is your stiffness after sitting, lying, or resting later in the day?

None	mild	moderate	severe	extreme
☐	☐	☐	☐	☐

5. The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours, in your knees.

What degree of difficulty do you have with:

		None	mild	moderate	severe	extreme
A. Descending (going down) stairs	A.	☐	☐	☐	☐	☐
B. Ascending (going up) stairs	B.	☐	☐	☐	☐	☐
C. Rising from sitting	C.	☐	☐	☐	☐	☐
D. Standing	D.	☐	☐	☐	☐	☐
E. Bending to floor	E.	☐	☐	☐	☐	☐
F. Walking on a flat surface	F.	☐	☐	☐	☐	☐
G. Getting in/out of car	G.	☐	☐	☐	☐	☐
H. Going shopping	H.	☐	☐	☐	☐	☐
I. Putting on socks/stockings	I.	☐	☐	☐	☐	☐
J. Rising from bed	J.	☐	☐	☐	☐	☐
K. Taking off socks/stockings	K.	☐	☐	☐	☐	☐
L. Lying in bed	L.	☐	☐	☐	☐	☐
M. Getting in/out of bath	M.	☐	☐	☐	☐	☐
N. Sitting	N.	☐	☐	☐	☐	☐
O. Getting on/off toile	O.	☐	☐	☐	☐	☐
P. Heavy domestic duties (mowing the lawn, lifting heavy grocery bags)	P.	☐	☐	☐	☐	☐
Q. Light domestic duties (such as tidying a room, dusting, cooking)	Q.	☐	☐	☐	☐	☐

(a)

구분	항목과 평가내용	평가				
	통증	없음 (0점)	약간 (1점)	보통 (2점)	심함 (3점)	매우심함 (4점)
1	평지를 걸을 때					
2	계단을 오르내릴 때					
3	밤에 잠을 잘 때 (수면을 방해하는 통증)					
4	(의자에)앉아 있을 때 혹은 누워있을 때					
5	똑바로 서 있을 때					
항목점수						

	경직	없음 (0점)	약간 (1점)	보통 (2점)	심함 (3점)	매우심함 (4점)
1	아침에 막 잠에서 깼을 때 느끼는 뻣뻣한 정도는 얼마나 심합니까?					
2	오후에 (의자에)앉거나, 눕거나, 쉬고 난 후에 느끼는 뻣뻣한 정도는 얼마나 심합니까?					
항목점수						

	신체적 기능	없음 (0점)	약간 (1점)	보통 (2점)	심함 (3점)	매우심함 (4점)
1	계단을 내려갈 때					
2	계단을 올라갈 때					
3	(의자에)앉아 있다가 일어설 때					
4	서 있을 때					
5	바닥으로 몸을 구부릴 때					
6	평지를 걸을 때					
7	승용차나 버스를 타거나 내릴 때					
8	시장을 보러갈 때					
9	양말이나 스타킹을 신을 때					
10	이부자리에서 일어날 때					
11	양말이나 스타킹을 벗을 때					
12	이부자리에 누울 때					
13	욕조에 들어가고 나올 때					
14	(의자에)앉아 있을 때					
15	양변기에 앉거나 일어설 때					
16	힘든 집안일을 할 때					
17	가벼운 집안일을 할 때					
항목점수						

(b)

Figure 7. WOMAC and K-WOMAC questionnaire

2.3.4. Pressure Pain Threshold (PPT)

Pressure Pain Threshold (PPT) is a subjective pain intensity indicator measured using a pressure algometer to determine the pressure value at which pain is felt when a specific area is pressed. It is effective in exploring physiological and pathological mechanisms and is reliably used in clinical settings [27-29]. PPT quantifies pressure changes in the most painful area, making it highly effective for monitoring individual pain level changes over time. Research has shown that women tend to have lower thresholds than men.[31-33] In this study, changes in the pressure pain threshold (PPT) at the most sensitive points of the spinal pain trigger were measured at 4 weeks and 6 weeks in comparison to the baseline (0 weeks).

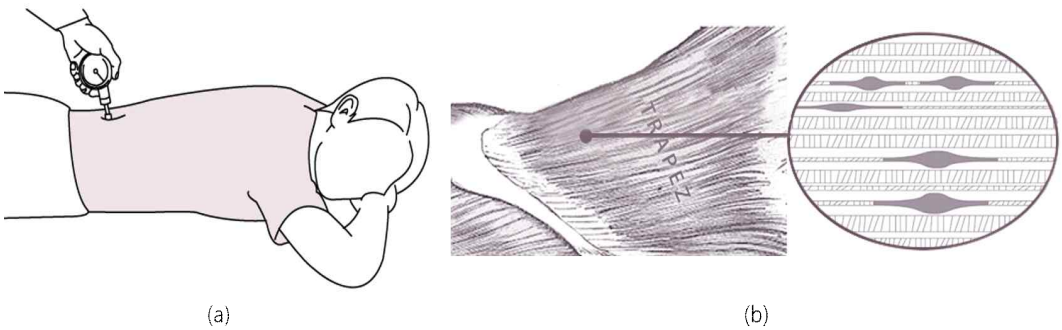


Figure 8. Example of PPT (Pressure Pain Threshold) Measurement
(a) assessing PPT with a pressure algometer. (b) instances of pain-triggering areas in the muscle

2.3.4. Measurement of Anatomical Functional Changes through General Radiography

The assessment of spinal tilt angle and Cobb's angle serves as important clinical indicators for assessing spinal structure and posture. X-ray imaging is used to evaluate spinal curvature and alignment, and this method is noted for having high reliability for such assessments.[36]

Changes in sacral tilt angle and scoliosis angle were evaluated at the 6-week mark in comparison to the baseline(0 weeks) using standard radiographic imaging. The purpose of this evaluation was to identify anatomical changes in spinal alignment and curvature following treatment. The Cobb technique, a traditional technique for measuring spinal deformities, particularly the degree of scoliosis, was used for radiographic analysis.

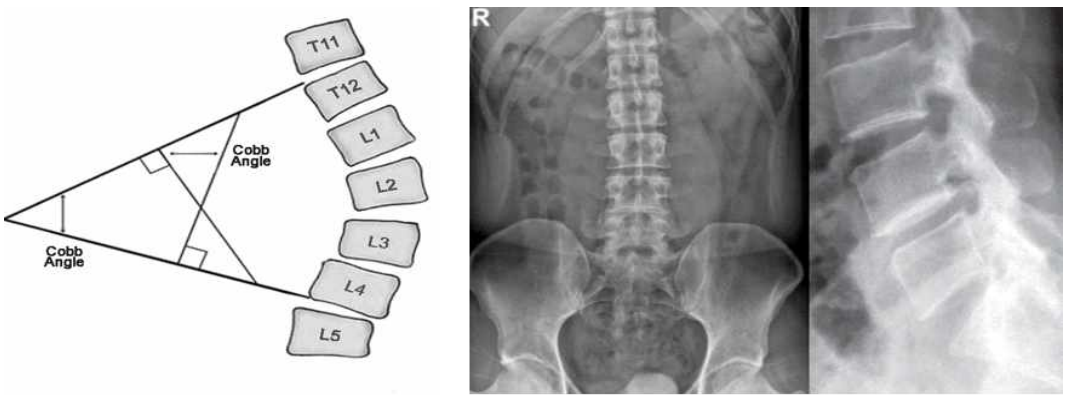


Figure 9. Anatomical analysis
(a) Cobb angle calculation method, (b) Standard radiographic image

2.4. Statistics

Statistical analysis for this research was performed utilizing the Statistical Analysis System (ver 9.4, SAS Institute Inc., USA) and R Studio (ver 4.1.3, R Studio, Inc., USA). Continuous data from all participants in this clinical trial were systematically analyzed as mean, standard deviation, minimum, maximum, and median values. For qualitative data, frequencies and percentages were provided. Differences between the experimental and control groups were assessed using the two-sample t-test for continuous variables (or the Wilcoxon rank-sum test if the normality assumption was not met). Comparisons of categorical variables were analyzed using Pearson's chi-square test (or Fisher's exact test was used if the expected frequency in any cell was less than 5 or accounted for more than 20% of the total frequency). Statistical significance was defined at a one-sided level of 2.5% and a two-sided level of 5%.

To statistically validate the differences in data changes measured three times from the same individuals, the Linear Mixed Model (LMM) approach was employed. The LMM statistical analysis model identifies relationships among variables by accounting for correlations among multiple observations. This model is especially beneficial for managing correlated or nested data, such as repeated observations or hierarchical arrangements.[37]

3. Results

3.1. Analysis results at each time points for evaluation variables

The two groups, experimental (18 participants) and control (18 participants), which were divided by means of random assignment based on age and gender, exhibited similar patterns in the distribution of pain complaint areas, with no statistically significant differences at the initial screening point.

As shown in Table XX, when analyzing the differences in pressure pain threshold (PPT), K-WOMAC scores, and Visual Analog Scale (VAS) scores between the two groups at each time point, the VAS scores showed a significantly greater reduction in the experimental group compared to the control group at both the 4-week and 6-week marks. While the PPT and K-WOMAC scores showed greater improvement in the experimental group, the differences between the two groups were not statistically significant at any time point.

Table 4. characteristics of overall variables

Classification		Control	Experimental	p-value
week 0 (baseline)	mean of PPT (SD) (kg)	6.4 (2.57)	6.19 (2.25)	0.7921
	mean of K-WOMAC (SD) (score)	50.22 (11.89)	55.06 (10.71)	0.2089
	mean of VAS (SD) (mm)	60.06 (8.88)	64.44 (12.95)	0.2439
week 4 (after treatment)	mean of PPT (SD) (kg)	6.99 (2.43)	8.02 (2.22)	0.1940
	mean of K-WOMAC (SD) (score)	41.67 (17.33)	32.61 (12.73)	0.0829
	mean of VAS (SD) (mm)	47.56 (15.27)	35.22 (10.52)	0.0079 *
week 6 (follow up)	mean of PPT (SD) (kg)	7.86 (2.48)	8.06 (2.1)	0.7954
	mean of K-WOMAC (SD) (score)	35.72 (18.12)	27.5 (13.24)	0.1293
	mean of VAS (SD) (mm)	46.94 (17.88)	31.56 (11.89)	0.0045 *

Note: * $p < 0.05$ is significant at $\alpha = 0.05$.

3.2. Results of temporal changes for evaluation variables

Analyzing the mean values of variable changes at each time point indicated that the Pressure Pain Threshold (PPT) did not show statistically significant differences at any specific time point. For the K-WOMAC, notable differences were noted between Week 0-4 and Week 0-6, but not between Week 4-6. The Visual Analog Scale (VAS) showed significant differences in the mean values of changes between Week 0-4 and Week 0-6.

Table 5. the mean value changes from baseline to 4 and 6 week

Category	Baseline to week 4			Week 4 to week 6			Baseline to Week 6		
	Control	Experimental	*p*-value	Control	Experimental	*p*-value	Control	Experimental	*p*-value
PPT (kg)	0.59 (2.07)	1.84 (2.56)	0.118	0.86 (1.58)	0.04 (1)	0.069	1.46 (2.13)	1.87 (2.23)	0.572
K-WOMAC (score)	−8.56 (14.77)	−22.44 (9.21)	0.001*	−5.94 (14.11)	−5.11 (8.36)	0.830	−14.5 (11.33)	−27.56 (10.25)	0.001**
VAS (mm)	−12.5 (16.82)	−29.22 (13.02)	0.002*	−0.61 (11.39)	−3.67 (5.43)	0.314	−13.11 (16.43)	−32.89 (14.01)	0.001**

Note: * $p < 0.05$ and ** $p < 0.001$ are significant at $\alpha = 0.05$.

3.3. Results of temporal changes for each variables

3.3.1 Results of VAS Analysis Using the LMM Model

To evaluate changes in pain at each time point, the differences in Visual Analog Scale (VAS) scores were analyzed using the Linear Mixed Model (LMM) technique. As shown in Table 7, the VAS scores decreased significantly over time in both the experimental and control groups. Furthermore, when comparing the degree of reduction between the two groups, the experimental group showed a statistically significant greater reduction in mean VAS scores compared to the control group (P-value < 0.05).

Table 6. Results of VAS Change Analysis

VAS (mm)	Estimated Mean	t-value	*p*-value
Control	51.52 (2.53)	20.35	<0.0001 **
Experimental	43.74 (2.53)	17.28	<0.0001 **
Control vs. Experimental	7.78 (3.58)	2.17	0.0369 *

Note: * $p < 0.05$ and ** $p < 0.001$ are significant at $\alpha = 0.05$.

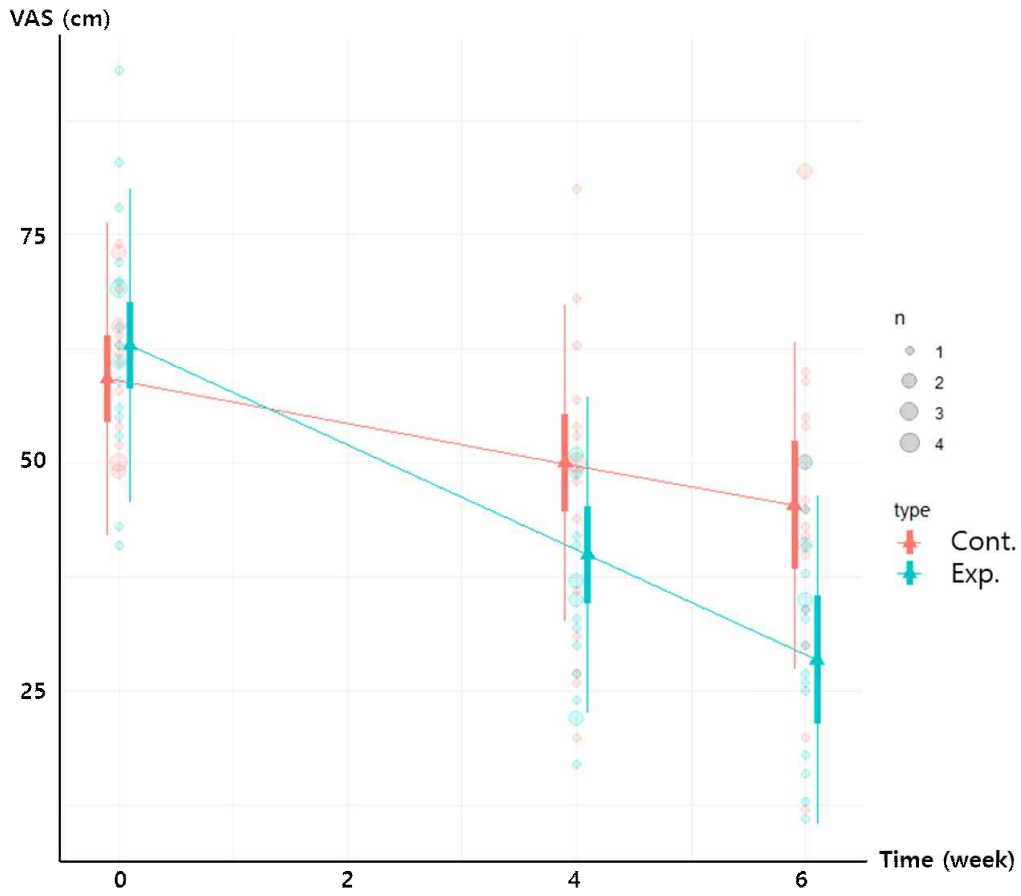


Figure 10. VAS changes according to time (week)

3.3.2 Results of K-WOMAC Analysis Using the LMM Model

The changes in K-WOMAC scores at each time point were analyzed using the Linear Mixed Model (LMM) method. The results indicated that K-WOMAC scores significantly decreased at each of the three time points. When comparing the degree of reduction, the experimental group showed a greater reduction, although this difference was not statistically significant (p-value: 0.691).

Table 7. Results of K-WOMAC Change Analysis

K-WOMAC (Score)	Estimated Mean	t-value	*p*-value
Control	42.97 (2.99)	14.38	<0.0001 **
Experimental	41.28 (2.99)	13.81	<0.0001 **
Control vs. Experimental	1.69 (4.23)	0.4	0.691

Note: * $p < 0.05$ and ** $p < 0.001$ are significant at $\alpha = 0.05$.

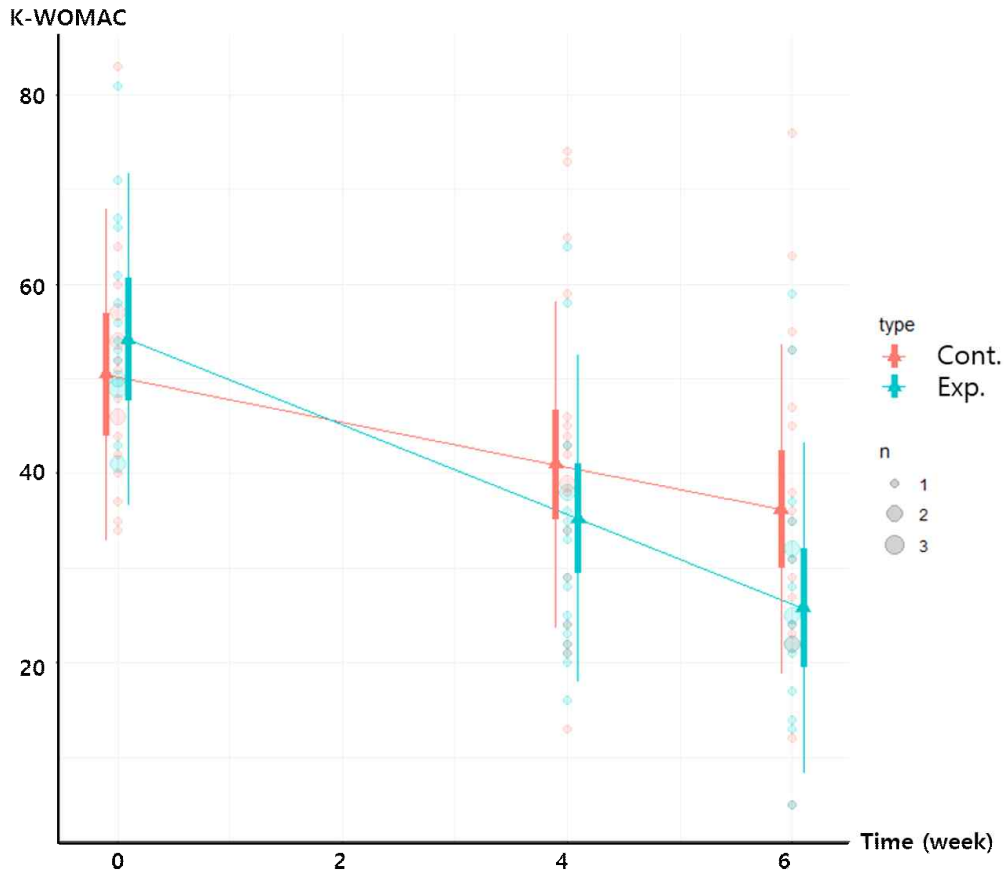


Figure 11. K-WOMAC changes according to time (week)

3.3.3 Results of PPT Analysis Using the LMM Model

The changes in Pressure Pain Threshold (PPT) scores at each time point were analyzed using the Linear Mixed Model (LMM) method. The results indicated that PPT scores significantly increased at each of the three time points. When comparing the degree of increase between experimental and control group, the experimental group exhibited an increase that exceeded that of the control group, though this difference was not statistically (p-value: 0.6233). The analysis suggests that pain sensitivity improved in both groups, as evidenced by the improvement in PPT scores, but the differences were not statistically significant.

Table 8. Results of PPT Change Analysis

PPT (kg)	Estimated Mean	t-value	*p*-value
Control	7.08 (0.48)	14.7	<0.0001 **
Experimental	7.42 (0.48)	15.4	<0.0001 **
Control vs. Experimental	−0.34 (0.68)	−0.5	0.6233

Note: * $p < 0.05$ and ** $p < 0.001$ are significant at $\alpha = 0.05$.

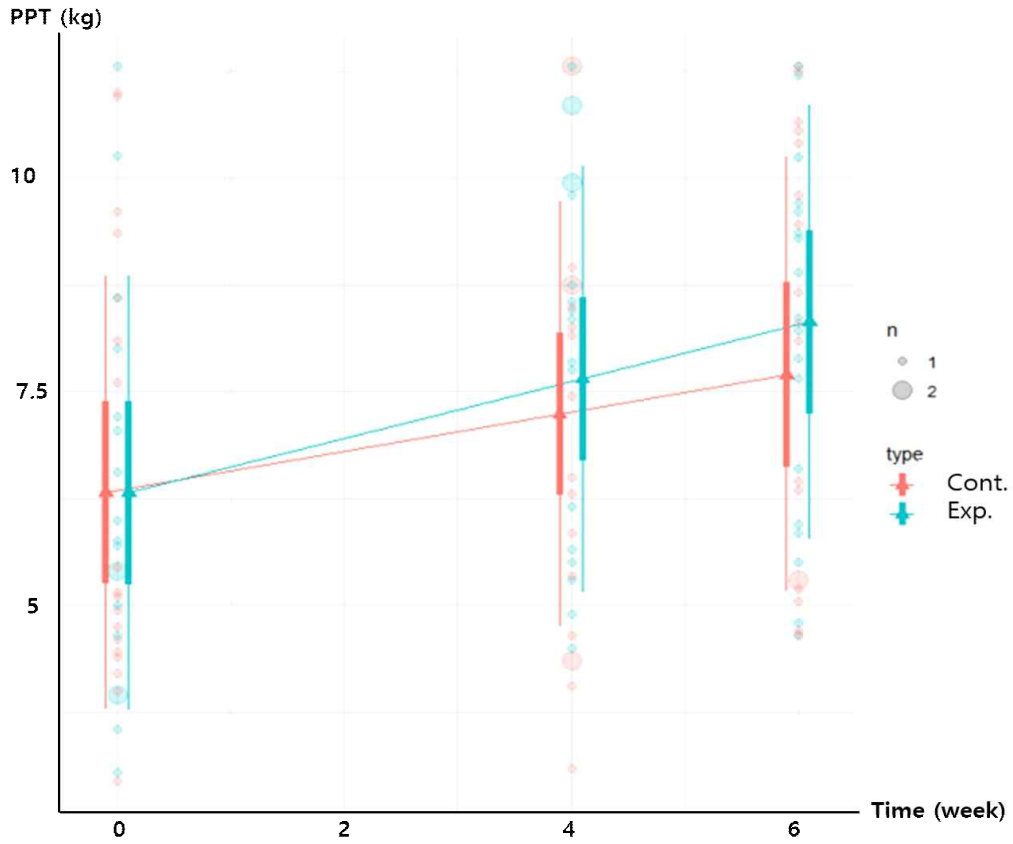


Figure 12. PPT changes according to time (week)

3.3.4. Analysis Results of Anatomical Changes via Standard radiographic

Comparison of sacral tilt angle and Cobb's angle measurements between baseline (0 weeks) and the 6-week mark using standard radiographic imaging revealed no distinct anatomical changes. The measurements did not indicate significant differences in spinal alignment or curvature over the study period.

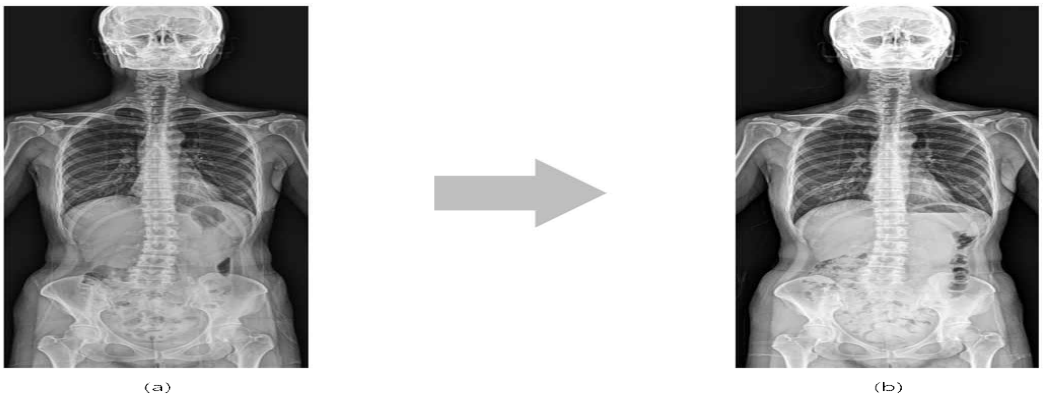


Figure 13. Anatomical analysis result using x-ray imaging;
(a) Baseline (0 Week), (b) Week 6

3.3.5. Analysis of Safety Evaluation

Among the 36 participants, there was one case of abdominal pain and one case of coughing. The participant experiencing abdominal pain was diagnosed with a gallbladder cyst, and the participant presenting with a cough was diagnosed with COVID-19. Both cases were determined to be unrelated to the medical devices utilized in this clinical trial. After receiving appropriate medical care, both participants were able to complete the clinical trial.

4. Discussion and Conclusion

Spinal pain is a leading cause of disability, affecting over 60% of adults across various age groups, thereby making it the most prevalent condition. Additionally, spinal pain frequently accompanies daily life constraints and discomfort, affecting mental health and overall well-being.[3,5] Thus, appropriate interventions are crucial to improve the quality of life.[3,38] Treatments for spinal pain include both operative and conservative approaches. Conservative treatments are frequently favored for individuals with milder pain or those who are worried about the potential adverse effects of surgery.[39] In several countries in Eastern Europe and Asia, heat therapy and spinal vibration massage devices intended for home use are widely employed. These devices are indicative a common form of non-invasive treatment, specifically involving heat and massage.[15,16]

Previous studies examining the mechanisms of pain relief via heat and massage have shown that heat activates thermo-receptors in both the deeper tissues and skin, resulting in the closure of the pain control gate according to the gate control theory.[40] This modulation of the pain control system results in pain reduction. Massage, on the other hand, triggers the pain modulation system in the nervous system, promoting recovery via muscle stretching and enhancing the release of pain-relieving mediators.[41] Furthermore, massage has been shown to increase levels of dopamine and serotonin, reduce cortisol, and normalize motor functions. Additionally, it has been suggested that heat and massage therapies enhance parasympathetic nervous activity while also enhancing sympathetic nervous system activity, indicating an overall increase in autonomic activity.[18]

This study aimed to assess the clinical significance of pain relief, improvement in daily function, and changes in anatomy resulting from the use of heat therapy in conjunction with spinal twisting massage in individuals suffering from chronic non-specific spinal pain, building on prior research findings in this area. A control group receiving only heat and vibration massage was used for comparison to verify effectiveness of the experimental intervention. The spinal twist massage used in the the experimental group includes four massage rollers strategically positioned horizontally that move in three dimensions (diagonally) to administer massage. This technique involves twisting adjacent vertebrae in opposite directions, the massage aims to improve spinal flexibility. The control group received conventional heat application and vibration massage, where the rollers moved horizontally using body pressure to provide the massage.

The primary findings of this study showed a significant reduction in pain severity, as assessed by VAS at 4 and 6 weeks relative to baseline (0 weeks) ($p < 0.05$). The experimental group also demonstrated a statistically significant decrease in pain score compared to the control group. These outcome was derived from comparisons between the two groups ($p < 0.05$). In assessing daily living function, as assessed by K-WOMAC, showed significant decreases in scores at at 4 and 6 weeks relative to baseline (0 weeks) ($p < 0.05$). Although there was no statistical significance in the comparison between the two groups, the experimental group displayed a greater reduction in K-WOMAC scores. This implies that heat and spinal twisting massage not only alleviate pain but also enhance physical mobility. The analysis of PPT score fluctuations at each time point showed a statistically significant rise($p < 0.05$). Additionally, the experimental group displayed a more pronounced increase compared to the control group, aalthough

this disparity did not reach statistical significance. Consistent with prior research indicating the effectiveness of thermal massage devices in alleviating pain, mood, and stress improvement[18,19], this study confirmed that applying heat therapy and spinal twisting massage effectively alleviates pain and enhances functional results in patients suffering from chronic non-specific spinal pain.[18-20,22,23] Notably, the outcomes indicated a stronger effect of heat and spinal twist massage compared to previous studies using conventional heat therapy or basic vibration massage. Moreover, this research did not report tthe adverse effects, such as localized soreness and discomfort, observed in So et al.'s study on widely employed heat and massage devices in the Middle East, Europe, and Asia.[24]

The study findings also indicated that using heat and spinal twisting massage for short-term treatment did not lead to any significant anatomical structural changes. Nonetheless, interestingly, it seems to offer superior pain relief for individuals suffering from chronic non-specific spinal pain compared to basic vibration and heat massages. The combination of spinal twisting massage and basic vibration therapy could potentially provide advantages for individuals coping with chronic non-specific spinal pain. Spinal twisting enhances spinal flexibility and mobility, whereas vibration massage promotes muscle relaxation and relieves tension. By combining these techniques, therapists can potentially amplify therapeutic effects and provide a holistic approach to managing spinal pain.

However, there are several limitations to this study. Although the study demonstrated significant pain relief and improved function with heat therapy and spinal twisting massage for chronic non-specific spinal pain, the study did not explore long-term effects or potential differences in treatment response across various patient subgroups. Moreover, this study did not assess how the

effectiveness of heat and spinal twisting massage compares to other conservative therapies or interventions beyond basic vibration massage.

This study sought to examine the clinical effects of heat therapy and spinal twisting massage on patients suffering from chronic non-specific spinal pain. Due to constraints in subject recruitment, study duration, and budgetary considerations, the study was limited to a particular age group, and anatomical changes were not observed. Moreover, focusing on clinical benefit resulted in he oversight of physiological and biochemical processes. Nevertheless, the study findings highlight the promising role of spinal twisting massage as a novel therapeutic strategy for reducing pain and enhancing daily functioning in individuals suffering from chronic non-specific spinal pain. Future studies could integrate quantitative analysis and simulation methodologies in order to explore the best direction and intensity of the stimuli required to maximize therapeutic benefits of spinal twist massage. Additionally, extended(long-term) clinical trials involving participants of varying ages, increased sample sizes, and variations in the frequency of treatment, along with investigations into physiological and biochemical mechanisms, are expected to yield further improvements in treatment outcomes.

References

1. 건강보험심사평가원 보건의료빅데이터개방시스템, 척추부관절증 통계자료, 2015-2019, http://opendata.hira.or.kr
2. Aranjan, L.K.; Arunasalam, P.; Lalith, S.W. Chronic low back pain and its association with lumbar vertebrae and intervertebral disc changes in adults. A case control study. Int. J. Rheum. Dis. 2018, 21, 602–610.
3. Cieza, A.; Causey, K.; Kamenov, K.; Hanson, S.W.; Chatterji, S.; Vos, T. Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: A systematic analysis for the Global Burden of Disease Study 2019. Lancet 2020, 396, 2006–2017.
4. Massimo, A.; Silvana, M.; Fabana, S.; Adriana, V.; Maurizio, M.; Christian, C.; Marco, B.; Maria, E.M.; Guido, F. Mechanisms of low back pain: A guide for diagnosis and therapy. F1000Research 2016, 5, 1–11.
5. Van Tulder, M.; Malmivaara, A.; Esmail, R.; Koes, B. Exercise therapy for low back pain: A systematic review within the framework of the cochrane collaboration back review group. Spine 2000, 25, 2784–2796.
6. Maher, C.; Underwood, M.; Buchbinder, R. Non-specifc low back pain. Lancet 2017, 389, 736–747.
7. Bogduk, N.; What's in a name? The labelling of back pain. Med. J. Aust. 2000, 173, 400–401.
8. Parati, G.; Saul, J.P.; Rienzo, M.; Mancia, G. Spectral analysis of blood pressure and heart rate variability in evaluating cardiovascular regulation. A critical appraisal. Hypertension 1995, 25, 1276–1286.

9. Morteza, D.; Farinaz, F. The efficacy of thermotherapy and cryotherapy on pain relief in patients with acute low back pain, a clinical trial study. J. Clin. Diagn. Res. 2014, 8, 01–04.
10. Kyselovic, J.; Masarik, J.; Kechemir, H.; Koscova, E.; Turudic, I.I.; Hamblin, M.R. Physical properties and biological effects of ceramic materials emitting infrared radiation for pain, muscular activity, and musculoskeletal conditions. Photodermatol. Photoimmunol. Photomed. 2023, 39, 3–15.
11. Galloway, S.D.; Watt, J.M. Massage provision by physiotherapists at major athletics events between 1987 and 1998. Br. J. Sport. Med. 2004, 38, 235–236.
12. Imamura, M.; Furlan, A.D.; Dryden, T.; Irvin, E. Evidence-informed management of chronic low back pain with massage. Spine J. 2008, 8, 121–133.
13. Furlan, A.D.; Giraldo, M.; Baskwill, A.; Irvin, E.; Imamura, M. Massage for low-back pain. Cochrane Database Syst. Rev. 2015
14. Bellido-Fernández, L.; Jiménez-Rejano, J.J.; Chillón-Martínez, R.; Gómez-Benítez, M.; De-La-Casa-Almeida, M.; Rebollo-Salas, M. Effectiveness of massage therapy and abdominal hypopressive gymnastics in nonspecific chronic low back pain: A randomized controlled pilot study. J. Evid. Based Complement. Altern. Med. 2018
15. Dmochowski, J.P.; Khadka, N.; Cardoso, L.; Meneses, E.; Lee, K.; Kim, S.; Jin, Y.; Bikson, M. Computational modeling of deep tissue heating by an automatic thermal massage bed: Predicting the effects on circulation. Front. Med. Technol. 2022, 4, 925554.
16. Kim, K.-E.; Park, J.-S.; Cho, I.-Y.; Yoon, Y.-S.; Park, S.-K.; Nam,

S.-Y. Use of a spinal thermal massage device for anti-oxidative function and pain alleviation. Front. Public Health 2020, 8, 493.

17. Lee, M.H.; Kim, K.E.; Jang, H.Y.; Cho, I.Y. The effectiveness of using a spinal column thermal massage device on muscle pain. J. Korea Converg. Soc. 2020, 11, 361–368.
18. Yamany, A.; Hamdy, B. Effect of sequential pneumatic compression therapy on venous blood velocity, refilling time, pain and quality of life in women with varicose veins: A randomized control study. J. Phys. Ther. Sci. 2016, 28, 1981–1987.
19. Lee, Y.H.; Park, B.N.R.; Kim, S.H. The Effects of Heat and Massage Application on Autonomic Nervous System. Yonsei Med. J. 2011, 52, 982–989.
20. Cantillo Bermúdez, J.; Rodríguez Sarmiento, L.A.; Vaca-González, J.J.; Fonseca Velásquez, A. Electromagnetic fields as a non-invasive alternative therapy for the treatment of musculoskeletal diseases. J. Appl. Res. Technol. 2022, 20, 245–259.
21. Yoon, Y.S.; Yu, K.P.; Lee, K.J.; Kwak, S.Y.; Kim, J.Y. Development and Application of a Newly Designed Massage Instrument for Deep Cross-Friction Massage in Chronic Non-Specific Low Back Pain. Ann. Rehabil. Med. 2012, 36, 55–65.
22. Joshua, W.; Noninvasive and Alternative Management of Chronic Low Back Pain (Efficacy and Outcomes). Neuromodulation 2014, 17, 24–30.
23. Sakpal, T.V. Sample size estimation in clinical trial. Perspect. Clin. Res. 2010, 1, 67–69.
24. Marienke, V. A systemic review on the effectiveness of physical &

rehabilitation interventions for chronic non-specific low back pain. Eur. Spine 2011, 20, 19–39.

25. Roser, C.; Laurie, H.H. Nonpharmacologic therapies foracute and choric low back pain: A review of the evidence for an American pain society/American college of physicians clinical practice guideline. Ann. Intern. Med. 2007, 147, 492–504.
26. Sandra, E. Short-term effect of superficial heat treatment on paraspinal muscle activity, stature recovery, and psychological factors in patients with chronic low back pain. Arch. Phys. Med. Rehabil. 2012, 93, 367–372.
27. Shafshak, T.S.; Elnemr, R. The Visual Analogue Scale Versus Numerical Rating Scale in Measuring Pain Severity and Predicting Disability in Low Back Pain. J. Clin. Rheumatol. 2021, 27, 282–285.
28. Amiri, M.; Alavinia, M.; Singh, M.; Kumbhare, D. Pressure pain threshold in patients with chronic pain: A systematic review and meta-analysis. Am. J. Phys. Med. Rehabil. 2021, 100, 656–674.
29. Hong, C.; Current research on myofascial trigger points, pathophysiological studies. J. Musculoskelet. Pain. 1999, 7, 121–129.
30. Kim, Y.; Kim, K. Abdominal examination using pressure pain threshold algometer reflecting clinical characteristics of complementary and alternative medicine in Korea: A systematic review and a brief proposal. Medicine 2022, 101, e31417.
31. Fischer, A. Muscle pain syndromes and fibromyalgia. Pressure algom-etry for quantation of diagnosis and treatment outcome. J. Musculoskelet. Pain. 1998, 6, 1–32.
32. Fillingim, R.B. Sex, gender, and pain. In Principles of Gender-Specific

Medicine; Academic Press: Cambridge, MA, USA, 2023; pp. 769–792.

33. Isselee, H.; De Laat, A.; Bogaerts, K.; Lysens, R. Long-term fluctuations of pressure pain thresholds in healthy men, normally menstruating women and oral contraceptive users. Eur. J. Pain. 2001, 5, 583–587.
34. Dougados, M. Monitoring osteoarthritis progression and therapy. Osteoarthr. Cartil. 2004, 12, 55–60.
35. Song, R.Y.; Lee, E.O.; Bae, S.C. Effects of tai chi exercise on pain, balance, muscle strength, and perceived difficulties in physical functioning in older women with osteoarthritis: A randomized clinical trial. J. Rheumatol. 2003, 30, 2039–2044.
36. Gstoettner, M.; Sekyra, K.; Walochnik, N.; Inter- and intraobserver reliability assessment of the Cobb angle: Manual versus digital measurement tools. Eur. Spine. J. 2007, 16, 1587–1592.
37. Krause, M.; Refshauge, K.M.; Dessen, M.; Boland, R.; Lumbar spine traction: Evaluation of effects and recommended application for treatment. Man. Ther. 2000, 5, 72–81.
38. Øverås, C.K.; Johansson, M.S.; Campos, T.F.; Ferreira, M.L.; Natvig, B.; Mork, P.J.; Hartvigsen, J. Distribution and prevalence of musculoskeletal pain co-occurring with persistent low back pain: A systematic review. BMC Musculoskelet. Disord. 2021, 22, 91.
39. Park, J.H.; Park, H.S.; Shin, Y.I.; Lee, H.J. A study on the definition and development direction of manual therapy. J. Korean Phys. Ther. Sci. 2022, 29, 1–14.
40. Chandler, A.; Preece, J.; Lister, S. Using heat therapy for pain management. Nurs. Stand. 2002, 17, 40–42.

41. Corey, S.M.; Vizzard, M.A.; Bouffard, N.A.; Badger, G.J.; Langevin, H.M. Stretching of the back improves gait, mechanical sensitivity and connective tissue inflammation in a rodent model. PLoS ONE 2012, 7, e29831.

Abstract in Korean

만성기계적 통증 및 기능개선(또는 장애개선)에 대한 척추 비틀림 마사지 기법을 접목한 척추 온열마사지 장비의 임상 효과에 관한 연구

<지도교수 김성훈>

연세대학교 대학원 의학과

성 명 : 조승현

만성 비특이적 척추 통증의 유병률이 증가함에 따라 다양한 마사지 장치를 이용한 치료 중재의 사용이 빠르게 증가하고 있습니다. 그러나 특히 척추 비틀기와 관련된 메커니즘에 대한 연구는 제한적입니다. 본 연구는 만성 비특이적 척추 통증을 겪는 개인들에게 열 적용과 척추 비틀기 마사지 기법이 미치는 영향을 평가하기 위해 설계되었습니다. 총 36명의 참가자를 두 그룹으로 나누었습니다: 대조군(18명)과 실험군(18명). 실험군은 4주 동안 주 2회 열 치료와 척추 비틀기 마사지를 받았고, 대조군은 열 치료와 전통적인 진동 마사지 기법을 받았습니다. 효과는 시각적 아날로그 척도(VAS), 압력 통증 역치(PPT), 한국판 웨스턴 온타리오 및 맥마스터 대학(K-WOMAC) 지수, 척추 기울기, 콥스각을 사용하여 측정되었습니다.

연구 결과, VAS, K-WOMAC, PPT 점수는 두 그룹 모두에서 세 시간 지점에서 유의미하게 개선되었습니다. 특히 VAS 점수는 실험군에서 대조군에 비해 현저하게 감소하였으며(p-값: 0.0369), 이는 실험군이 대조군보다 통증 완화에 있어 더 큰 효과를 보였음을 의미합니다. 실험군 내에서 K-WOMAC 및 PPT 점수의 개선이 있었지만, 통계적 유의성은 확보되지 않았습니다. 또한, 척추 기울기와 콥스각은 기준선에서 6주차까지 유의미한 차이를 보이지 않았습니다.

본 연구는 만성 비특이적 척추 통증 환자에게 열 요법과 척추 비틀기 마사지가 통증 완화와 일상 기능 향상에 미치는 긍정적 영향을 확인하였습니다. 열과 척추 비틀기 마사지를 결합한 치료는 전통적인 열 요법과 진동 마사지를 결합한 방법보다 더 높은 효능을 보여주었습니다. 이는 기존의 보존적 치료법에 비해 새로운 치료 옵션으로서의 가능성을 시사합니다. 연구 결과는 열과 척추 비틀기 마사지가 자율 신경 활동을 전반적으로 향상시키고, 통증 완화와 신체 활동 개선에 기여할 수 있음을 보여줍니다.

그러나 이 연구에는 여러 제한점이 존재합니다. 본 연구는 장기적인 결과나 다양한 환자 하위 그룹 간의 치료 반응의 잠재적 변화를 조사하지 않았으며, 단순 진동 마사지 외의 다른 보존적 치료법이나 중재와 척추 비틀기 마사지 및 열 요법의 효과를 비교하지 않았습니다. 향후 연구에서는 다양한 참가자 연령대, 확장된 샘플 크기 및 치료 빈도의 변화를 포함한 장기 임상시험과 생리학적 및 생화학적 메커니즘에 대한 연구를 통해 치료 결과를 더욱 향상시킬 수 있을 것으로 기대됩니다.

핵심되는 말: 만성 비특이적 척추 통증, 척추 비틀림 마사지, 온열 치료, 한국판 WOMAC, 시각적 아날로그 척도